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ETHICAL ASPECTS OF IMMUNISATION SERVICES IN SOUTH AFRICA: IMPLICATIONS FOR LEGISLATION AND POLICY REVIEW.

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand Johannesburg, in partial fulfilment of the requirements for the degree of Master of Science in Medicine in the branch of Bioethics and Health Law, Steve Biko Centre for Bioethics.

Johannesburg, 2008

DECLARATION:

I Ntombenhle Judith Ngcobo (Myeni) declare that this research report “Ethical Aspects of Immunisation Services in South Africa: Implications for Legislation and Policy Review” submitted for assessment for the MSc Med (Bioethics and Health Law) is my own unaided work. I have followed the required conventions in referencing the thoughts and ideas of others. It is being submitted for the degree of Master of Science in Bioethics and Health Law in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.

……..

8th day of December 2008

DEDICATION:

In loving memory of my mother,

Andrina MaMhlongo Ngcobo

1921 - 1997

ABSTRACT

Immunisation is the most cost-effective public health intervention currently available. However, immunisation raises ethical conflicts as it may be considered a public good with little individual benefits. Considering the effectiveness of immunisation in controlling vaccine preventable infections and the constant threat of outbreaks from conditions like measles, refusal to participate in a universal immunisation programme is morally questionable. This research analyses the ethical issues brought up by universal immunisation in South Africa. It focuses on local practice and on selected risk benefit issues.

The research method used is literature search with analysis in the form of critical thinking and moral reasoning. The findings are that universal immunisation is ethically defensible based on various ethical theories and principles. South Africa's experience with the 2003 -2005 measles outbreak points to a *social contract* for individuals to immunise their children. The argument of taking personal risk for public good and the *no additional benefit argument once herd immunity is reached* (presented by Dawson), are refuted. Risk-benefit elements for each infectious condition and vaccine are continually changing. This demands an ongoing assessment of risk-benefit issues for each vaccine and targeted infections to ensure the use of vaccines with optimal safety levels that are appropriate in South Africa.

Recommendations are made on immunisation policy and legislation aimed at improving ethical practices of the immunisation service. Implementation of the recommendations will help ensure an immunisation programme that is proactive in addressing associated risks and should help eliminate litigation. The main recommendation of a legislated Compensation System for those who suffer severe adverse events following immunisation is directed at just distribution of benefits and burdens.

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Title of the Essay:

Ethical aspects of the immunisation services in South Africa: Implications for legislation and policy review.

Synopsis:

This research is an ethical analysis of the core ethical issues concerning immunisation services in South Africa. It analyses the ethical basis of universal immunisation using the various ethical theories. It tackles the conflicts of individual rights as opposed to public good and focuses on the conundrum of the moral acceptability of individuals and groups to refuse immunisation. Selected risk-benefit issues entailed are considered and a reference is made to immunisation policy and practice in South Africa. Concrete recommendations on legislation and policy review are made.

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Table of Contents

Nomenclature 7

1. Introduction and Literature Review 8

2. Methodology and Data Analysis 17

3. Immunisation as a Public Health Programme 18

3.1 Public Health and Bioethics: The Different Orientation 18

3.2 Immunisation as a Global Priority Intervention Strategy 22

3.3 The Need for Public Cooperation 23

3.4 Principles for making immunisation universal 25

4. Ethical Basis for Immunisation 28

4.1 Ethical Theories that Support Immunisation 28

4.2 Early Philosopher, John Stuart Mill 37

4.3 Principle Based Approach 40

4.4 Theories that Oppose Universal Immunisation 43

5. Repudiation of Ethical Objections to Immunisation 49

5.1 The Nature of Immunisation and Moral Conflicts 49

5.2 Risk and Benefit for Healthy individuals 50

5.3 Individual Protection versus Herd Protection 55

5.4 Social Contract 57

6. Group Refusal of Immunisation Services 61

7. The Specific Ethical Challenges of EPI-SA 65

7.1 Immunisation Policy and the setting 65

7.2 Risk in relation to EPI vaccines 72

7.3 Monitoring of Adverse Events Following Immunisation (AEFI) 78

8. Recommendations and Conclusion 81

9. References 84

Annexure A : Human Research Ethics Committee Clearance Certificate

Nomenclature

AFP	Acute Flaccid Paralysis
AEFI	Adverse Event Following Immunisation
BCG	Bacillus Calmette - Guerin
CDC	Centre for Disease Control and Prevention
DT	Diphtheria and Tetanus
DPT -Hib	Diphtheria Pertussis and Tetanus - Haemophilus Influenzae type b
EPI	Expanded Programme on Immunisation
EPI - SA	Expanded Programme on Immunisation in South Africa
IPV	Inactivated Polio Vaccine
MCC	Medicine Control Council
NCL	National Control Laboratory
NDEMC	National Adverse Drug Event Monitoring Centre
NDOH	National Department of Health
OPV	Oral Polio Vaccine
PEI	Polio Eradication Initiative
PHC	Primary Health Care
SA	South Africa
SIAs	Supplementary Immunisation Activities
UK	United Kingdom
UNICEF	United Nations Children's Educational Fund
USA	United States of America
VAPP	Vaccine Associated Paralytic Polio
VcDPV	Circulating Vaccine Derived Poliovirus
VPDs	Vaccine Preventable Diseases
WHA	World Health Assembly
WHO	World Health Organisation
WPV	Wild Poliovirus

1. Introduction and Literature Review

Immunisation is one of the most cost-effective public health interventions. Consequently it has been appropriately referred to as one of the greatest public health achievements of the twentieth century (CDC 1999: 243-248). The World Health Organisation estimates that immunisation saves over two million lives per year (WHO 2005: 288), and has the potential to save even more. The gains made by immunisation include amongst others: smallpox eradication, the significant decline in measles cases and the pending polio eradication. The benefits of immunisation extend beyond the control and elimination of infectious diseases; immunisation can help control antibiotic resistance and has resulted in a reduced incidence of hepatocellular carcinoma (Andre 2003:593-595). Furthermore, immunisation programmes have helped to improve the primary health care infrastructure in developing countries. There is an understanding that a properly implemented immunisation programme will have positive impact on economic growth; particularly in developing countries through improvement in survival as good health forms the basis for economic growth (Bloom 2005:15-39). The broad value of immunisation and its economic impact has been acknowledged; the 1993 World Development Report, "Investing in Health", listed immunisation as the first component of an essential public health package (World Bank 1993 cited in Bloom 2005). It is evident that immunisation does not just benefit the present generation; its benefits will continue to be reaped by many more generations to come.

The immunisation programme, similar to other public health programmes is in keeping with the consequence based theory of utilitarianism, which pursues the principle of "greatest good for the great number". Utilitarianism plays a significant role in the

development of public policy based on its focus on utility (Beauchamp 1994: 55). Utilitarianism provides for an objective assessment of everyone's interest and aims to maximise benefits. This is true for immunisation, as it aims for individual protection and public good. Furthermore immunisation encompasses the principles of beneficence and justice because it promotes health and welfare of individuals and the public, based on a collective effort.

Despite the unquestionable benefits of the immunisation programme worldwide, the acceptance of universal immunisation in developed countries has been a challenge. A number of vaccine preventable infections are no longer perceived by many to pose significant risk to individuals. Many adults living in developed countries and even some of their doctors graduating from medical school have not witnessed the misery that can be caused by vaccine preventable infections (Vernon 2003: 399-404; Obaro 2003: 1423-1431). Immunisation has come to face the failures of its own success. The very programme that led to eradication and virtual elimination of conditions that in the past caused a lot of human suffering and were a significant public health threat is now perceived to pose more risk from the side effects of the vaccines than the risk from the diseases it is meant to prevent. There may be a danger that communities in developed countries will soon forget the benefits of vaccines, including the ones which are still not available in the developing countries. There may be a tendency to dwell in the trivial, self limiting adverse effects of vaccination (Vernon 2003: 399-404).

Opposition to universal immunisation presents from many fronts: the anti vaccination movements; alternative health care practitioners and their clients; the World Wide Web contains numerous anti vaccination articles; religious groups and other individuals

opposed to immunisation. Freed (1996), indicates that the media plays a big role in creating a harsh climate for immunisation services and raises concerns on vaccine safety that cannot be underestimated. The information published by the media can have far reaching consequences; yet this information is often biased, distorted and lacks scientific facts (Freed 1996:1869-1872). Furthermore, published information may be biased towards reporting more on vaccine risks than on benefits. Certain medical controversies and lack of agreement in the medical community on the side effects and risk posed by vaccines have further fuelled opposition to immunisation, caused fear and uncertainty amongst parents and care givers. The controversy around Measles Mumps Rubella (MMR) vaccine and the unproven allegations that this vaccine is associated with autism is one good example (Salmon 2006:436-442; Clements 2003:22-26).

Parents base their decisions on information available to them, even though it may have no scientific basis and may be misrepresented facts. An individual when weighing the benefits and the risks may end up opting not to immunise her child based on available information. There is no doubt that as long as the relevant organisms have not been eradicated, as more and more individuals choose to do what they believe is in their best interest and do not immunise their children, the immunisation coverage drops. With time re-emergence and outbreaks of previously controlled infections occur. Examples of re-emerging diseases related to a drop in immunisation coverage include outbreaks of pertussis and measles in the United States and United Kingdom, outbreaks of diphtheria in Russia (Salmon 2006: 436-442; Isaacs 2004: 392-396 & Bradley 1999: 330-334). It is evident that those who oppose universal immunisation, claiming that there is more risk from vaccines than from the diseases targeted may be misleading the parents and the public. It is doubtful that anyone who does this may be bold and honest enough to stand

up and acknowledge misleading the people when outbreaks occur (Clements 2003: 22-6). Based on the benefits of immunisation and the challenges mainly developed countries face in increasing immunisation coverage, immunisation services are compulsory in some developed countries.

The intrinsic factors of a universal immunisation programme form the basis of moral conflicts. Immunisation protects individuals, and when large enough numbers are immunised, a high level of population (herd) immunity is reached and public protection results. This brings up the conflict of individual rights and actions versus public good. Of essence to consider, notwithstanding individual rights, is that governments have a special interest in ensuring high immunisation coverage, due to its benefit of protecting the entire population.

Based on these qualities of an immunisation programme and the issues indicated earlier, refusal to participate in a universal immunisation programme (compulsory or voluntary), is morally questionable. The moral conflicts brought up by refusal of immunisation need to be addressed. To address the major aspect of this conflict, this research aims to: establish the moral basis of universal immunisation services in relation to ethical approaches, conduct an ethical analysis of the key arguments entailed in immunisation refusal, reflect on immunisation policy in South Africa, interrogate selected risk benefit issues and finally draw up recommendations for the immunisation services in South Africa.

There is a significant amount of literature on ethics and immunisation, however none has conducted a comprehensive ethical analysis with specific focus on a developing

country like South Africa, which is the object of this study. Paul and Dawson (2005: 393-406) consider ethical issues that relate to the polio eradication programme in India. This work concentrates mainly on risk and benefits of the mass polio immunisation strategy as part of the global polio eradication effort and the risk of developing vaccine associated paralytic polio (VAPP). They also look at the issue of informed consent and disclosure on the risk associated with immunisation. Although, this work covers some important aspects which are of relevance to this research, the main focus was polio mass immunisation, its risk and associated ethical issues in India.

Dawson (2004) on “Vaccination and the Prevention Problem” critically reviews the objection to preventive medicine, using preventive vaccination. He brings up important concepts which are of relevance to this study. He maintains that, herd protection an important public good which is a benefit shared by individuals in society, should be acknowledged by individuals. He disputes the argument based on supposed inequities in risk. Dawson’s main focus is on comparing therapeutic vaccination and preventative vaccination.

The work of May and Silverman (2005:12-15) has concentrated on some aspects of group refusal of immunisation. This work looked at the legal limitation of government authority in relation to exemption from immunisation. Due to the fact that certain groups are more likely to appeal for exemption, this may have the undesirable effect of loss herd protection amongst that particular group, which may lead to disease outbreaks. May and Silverman’s work considers the complication that “government authority cannot single out specific groups to bear an infringement on liberty or to bear a burden”. In this case government has limitations in disallowing exemptions from immunisation in such

groups, particularly religious groups which have long been recognised as a protected characteristic. Whilst this work covers group refusal, it concentrates on the legal aspect of addressing this problem and the limitations faced by government authority. It does not focus on the ethical basis for group refusal and the implications thereof.

There is significant amount of literature on the justification for or the need for compulsory immunisation services in the United Sates of America and in the United Kingdom (Isaacs 2004: 392-396 and Bradley 1999: 330-334). Isaacs' work has relevance to this research, it considers the ethical basis for immunisation, looking at communitarian, consequentialism and the right based approaches; the risk benefit issues; herd immunity and the free riders. Their work has more focus on establishing the justification for compulsory services. Bradley's work is also on the need for compulsory immunisation in the United Kingdom. The focus is on a right based approach; right of parents to raise children according to their own standard, the right of children to receive health care and protection and the right of communities to be protected from vaccine preventable infectious diseases. Bradley's work does not cover the ethical basis of a universal immunisation programme. This research is an in-depth analysis of ethical issues, considers the local setting and specific country experience.

This research report is divided into eight (8) chapters. The first two chapters are the introduction and methodology. Chapters 3 to 7, form the main body of the report. Chapter three deals with immunisation as a public health programme. It outlines the different orientation of early bioethics and public health. It then looks at immunisation programme as a global intervention programme, prioritised in many countries. The

nature of the programme as it requires public cooperation and the principles for making immunisation universal are covered.

Chapter four (4) looks at the ethical approaches that can be considered to form the basis for a universal immunisation programme and those that may be opposed to immunisation. The major ethical approaches in relation to universal immunisation are considered. The ethical approaches referred to are: Utilitarian, Kantianism, Casuistry, Communism and Liberty. The reasoning of early philosopher, John Stuart Mill and his *"harm/harm to others principle"* is reviewed in relation to universal immunisation. The ethical principles are also briefly considered.

Chapter five (5) considers the argument that immunisation is aimed at public good whilst individuals take personal risk. This is considered in depth based on Dawson's (2004:515-530) argument, the prevention problem. The other argument by Dawson (2007:160-178) that once herd immunity is reached there is no additional benefit to society in individuals being vaccinated, therefore there is no moral obligation for individuals to subject themselves to immunisation, is refuted. This chapter considers closely the concept of the social contract as suggested by Freed (1996: 1869-1872). The concept of a social contract for all members of society to immunise their children is upheld, based on the obligation of individuals to contribute to society for the protection enjoyed by all.

Chapter six (6) considers briefly the area of group refusal. The factors which contribute to group refusal and the consequences are covered. Specific reference is made to the

suspension of polio immunisation activities in the Northern States of Nigeria from 2003 to 2004, and the consequences thereof.

Chapter seven (7) looks at specific ethical issues which relate to the expanded programme on immunisation in South Africa. The immunisation policy; the constraints faced at service delivery, adverse events following immunisation (AEFI) and the risk benefit issues as they relate to whole cell pertussis and oral polio vaccine are considered. This chapter deals with the need to closely monitor AEFI and to continually review the national immunisation policy as the epidemiology of the diseases targeted changes and newer, safer vaccine products become available.

Chapter eight (8) covers the recommendations and conclusion of the main findings of this research. Having conducted an ethical analysis of the conflicts raised and considered risk–benefit issues, the essay concludes with a set of concrete recommendations on revision of policy and legislation. The thesis of this research is that the recommendations will allow these instruments to respond appropriately to the ethical issues identified and will position the immunisation programme to respond to ethical and legal challenges faced to the benefit of society at large.

In most sections issues are presented in a generalised way as they apply to most immunisation settings; however the focus is on South Africa. [1] The terms immunisation and vaccination are used interchangeably. It is acknowledged that some may question such use. The understanding is that most have become accustomed to the use of the

[1] The focus of this research is on universal immunisation services offered through the Expanded Programme on Immunisation in South Africa (EPI-SA).

term immunisation where strictly speaking vaccination should have been used. Similarly, the terms herd protection and herd immunity will be used interchangeably.

The arguments used in this research are based on immunisation for contagious vaccine preventable infections (VPDs) like diphtheria, polio and measles, where the concept of herd immunity applies.[2] The immunisation: of adults, workers as part of health and safety programmes and immunisation in response to threats of bioterrorism are not the focus of this research. There is no specific focus on mass immunisation campaigns.

[2] Whilst immunisation for conditions like tetanus is recommended, a high level of immunisation coverage for such conditions has no effect of herd immunity, as vaccination protects only individuals and their unborn offspring in the case of tetanus.

2. Methodology and Data Analysis

Methodology

The method used in this study is literature search and ethical analysis of the issues raised in line with the objectives and included:

- Literature search and review, using appropriate key words
- The use of the World Wide Web to access and get references to relevant publications. Search engines used: PubMed / Medline, Google Scholar, Lexis Nexis and ProQuest
- Reflecting on material from scientific and academic textbooks; ethics, medical and medico-legal journal articles published on the topic of immunisation, ethics and public health
- Reflecting on current practices and policy of the immunisation programme in South Africa
- Analysing the ethical issues raised from these sources regarding immunisation services.

Data Analysis

Data was analysed in the form of critical thinking and moral reasoning on the main scientific and ethical issues involved in universal immunisation: public good versus individual rights, refusal of immunisation, the risk–benefit issues and experiences of the immunisation programme in South Africa in relation to measles outbreak. Reference is continuously made to the ethical and medico-legal articles sourced.

3. Immunisation as a Public Health Programme

3.1 Public Health and Bioethics: The Different Orientation

The early history of Bioethics is represented by two divergent approaches. The first is the Potter model. Van Rensselaer Potter, an oncologist working in the USA state of Wisconsin, first coined the term "bioethics". He used it to mean "life-ethics" and applied it to the practice of medicine within the scope long-range environmental concerns (Potter 1975: 299).[3]

At about the same time (± 1971), the Georgetown bioethics model emerged. This view looked at concrete medical dilemmas. The focus was on the "rights and duties of patients & healthcare professionals, rights & duties of research subjects & researchers, and the formulation of public policy guidelines for clinical care & biomedical research" (Reich 1994: 322-323). The Georgetown model was politically backed and became the predominant model for biomedical ethics in the USA and in many other countries. It was supported by Beauchamp and Childress' Principlist approach to Bioethics. The application of such principles became what is called the "Georgetown mantra".[4] Subsequently, application of the principles in medical practice involved mainly preserving the good of an individual, autonomy, and individual rights (Bayer 2004: 473-492; Callahan 2002: 169-196; Kass 2001: 1776-1782). It should be noted here that there has been a concerted movement, mainly because of environmental concerns to "reunite the bioethical twins [the Potter and Georgetown models] that have been separated since birth" (Reich 1995: 31).

[3] Potter postulated links between adverse environmental effects and cancer; his concern was that a new ethics, a bio (life) ethic was needed for the survival of the human species.
[4] Beauchamp and Childress' four principles of bioethics are: autonomy, non-maleficence, beneficence, and justice.

Currently, bioethics as a field is constantly re-defining itself reconsidering its orientation, attempting to stimulate perceptions of which things count, to clarify implications of excluding some issues and voices, and to illuminate the intellectual and moral culture that continues to shape it.

Public Health programmes, including immunisation raise a number of moral conflicts that are not adequately addressed by the initial focus of bioethics and thus require their own ethical appraisal (Callahan 2002: 169-196). The field of public health raises distinct questions, moral and legal conflicts which are in sharp contrast to the earlier focus of bioethics. The orientation of public health programmes is public good and societal benefit. Individual good, the focus of clinical medicine cannot determine the course of action in public health interventions. Coughlin (2006), Bayer (2004) and Callahan (2002) point out that, public health programmes (including the immunisation programme), are by their nature: paternalistic, utilitarian, communitarian and consequently put limits on individual rights.

The deep divide between the central commitment of earlier bioethics and the practice of public health has been acknowledged. Bayer (2004) has questioned the relevance of autonomy focussed bioethics in the role of public health and concludes:

> "May be bioethics cannot serve as a basis for thinking about balances required in the defence of public health…As we commence on the process of shaping an ethics of public health, it is clear that bioethics is a wrong place to start".

Whilst this research acknowledges the ethical conflicts brought about by public health practice, it refutes this conclusion. Bioethics offers a broad background to guide

decisions and practices. It is an unfortunate consequence that the greatly 'marketed' Georgetown model of bioethics (the four principles) was considered as the only way to look at ethical problems, while their foundations were less-highlighted.[5] For example, the focus on individualism and autonomy should be considered in the context of the USA where autonomy is a greatly emphasised cultural libertarian value. This concept, as numerous multi-cultural authors have emphasised, is often tempered by one's particular cultural background.[6] Moreover, it expresses the need for the roots of autonomy to be placed back in its original focus: that of respect for persons. Bioethics can indeed help address the dilemmas faced in public health practice as long as we do not equate public health ethics to clinical bioethics. Callahan (2002) and Kass (2001: 1776-1782) hold a similar view and suggest that instead of a focus on conflicts in bioethics and public health we should look at issues with a level of maturity to the benefit of both public health and bioethics.

An important difference in approaches is that of prevention versus treatment. Policy makers have a responsibility to implement public health interventions, as these provide high returns for a large number, are cost-effective and are mainly preventative in nature. Policy makers should therefore prioritise interventions that prevent the onset diseases, that is primary prevention measures. Primary prevention programmes like immunisation are much more desirable for the health of populations and individuals in comparison to secondary prevention measures, which merely limit disease progression.

[5] The four principles have their roots in a combination of deontology, utilitarianism and the works of W. D. Ross (Beauchamp and Childress 1994).

[6] See for example: Asai, A and Sakamoto, S. 2007. Self-determination of death in Japan: A review and discussion. *Eubios Journal of Asian and International Bioethics*, 17 (2): 35-40; Carlisle, S. and Hanlon, P. 2007. The complex territory of well-being: contestable evidence, contentious theories and speculative conclusions. *Journal of Public Health,* 6 (4).

It is the very nature of preventative public health programmes that brings about the ethical and legal conflicts, most of which are in sharp contrast to principlism. The main differences between public health and clinical medicine are that: the initiative for public health programmes comes from public health professionals and or government agencies, public health programmes are directed at public good and the pervasiveness of public health programmes which may interfere with individual lives (Dawson 2007: 2-3 ; Blum 2006: 273-281). These features are in sharp contrast to e.g. clinical medicine where an individual seeks healthcare (often from a single individual) due to an illness. Participants in a prevention programme are contrary to this as they are healthy or asymptomatic individuals. This creates a prerequisite for public health programmes to be vigilant on safety, as the level of risk tolerance becomes low. The pervasiveness of the programmes and public orientation creates the conflict of individual good versus public good. The question arises as to when can a public health intervention be enforced, putting limits on individual freedom?

However, public health is not aimed at violating or overriding individual rights, rather it is in a particularly challenging situation where the health of the public has to be protected while respecting individual rights and autonomy. This should be viewed as the main focus of public health ethics, which is referred to as a "dual responsibility" that must involve an interplay of protecting the welfare of individuals whilst maintaining the primary goal in public health, that of public welfare (Coughlin 2006).

This tension is a core feature of public health ethics. Suggestions as to the alleviation of such have been proposed by writers such as Gostin et al. (2003) who suggest that coercive measures which violate individual human rights are only acceptable when the

risk to the public's health is demonstrable, the intervention is likely to be effective and cost-effective, when it is not overly invasive, when it is distributed fairly amongst the population, and that the process for pursuing the intrusive intervention is legally just and publicly transparent. So, public health ethics in practice does recognise the links between human rights, community, as well as individual health (Mann 1996: 924-925); so to say that public health ethics ignores these important considerations is perhaps an oversimplification of the nature of public health ethics (Wynia 2005:6-8).

3.2 Immunisation as a Global Priority Intervention Strategy

Immunisation is a global public health intervention strategy. The World Health Organization (WHO) launched the Expanded Programme on Immunisation (EPI) in 1974, from which time additional antigens were added on the immunisation programme. Recognising the enormous benefits of immunisation, the United Nations (UN) and many countries consider the Expanded Programme on Immunisation as a priority programme. In keeping with this priority rating, UN agencies: WHO and UNICEF have a specific mandate to provide support and ensure effective immunisation programmes in developing and poorer countries of the world.

Furthermore, the UN Special Sessions and the World Health Assembly (WHA) have over the years adopted a number of resolutions on the control of vaccine preventable diseases. These include resolutions on: wild poliovirus eradication, measles control and the more recent resolution on the Global Immunisation Vision and Strategy (GIVS). GIVS was endorsed by the World Health Assembly in 2005 (WHA 2005); it aims for the control of vaccine preventable diseases through increasing global access to

immunisation services. UN member states have a mandate to implement these binding resolutions and ensure effective immunisation programmes in their countries.

3.3 The Need for Public Cooperation

The effectiveness of an immunisation programme and its ability to achieve control of infectious diseases demands that a large number of susceptible individuals be immunised. When a large majority of people in a community are immunised, disease transmission is interrupted and the risk of disease is significantly reduced. When such a level of population immunity is reached it is referred to as herd immunity with resultant herd protection. At this stage, individuals receive protection irrespective of whether they have contributed to this collective effort or not (Isaacs 2004). Consequently the incidence of the disease drops and individuals are less inclined to take the minimal risk of immunisation when they can be protected by herd immunity and the risk of the disease appears to be remote. This creates the "*Tragedy of the Commons*". Malone *et al* draws a striking analogy with that of a community arrangement for cattle to graze in a common pasture. Individuals keep on adding more of their own cattle to reap individual benefits, this eventually leads to overgrazing and defeats the community interest of maximising food production (Hardin 1965, cited in Malone 2003: 262-284). Similarly in the case of immunisation, as more and more individuals refuse to immunise their children, the level of population immunity drops, this eventually results in outbreaks and re-emergence of previously controlled infections. [7]

[7] This position is supported by others. See e.g. Blum, 2006; Salmon, 2004; and Bradley, 1999.

Public health now emphasises greater community empowerment and its greater participation, so in many respects the field has become more interdisciplinary and complex. It is evident that for an immunisation programme to be effective, public cooperation is required. A factor which may hinder community understanding of a vaccination programme is that contemporary community members (particularly parents) have never lived through an epidemic such as measles. This tends to diminish the perception of the need for vaccination while at the same time, the same parents may have heard about errors in medical interventions; this is referred to as the problem of 'misconceived risk' (May 2003). Media portrayals which exaggerate or trivialise the benefits and burdens of vaccination programmes can greatly effect public perceptions. So, public health personnel must consider media communication as an important factor in public health and community interactions. This is of particular importance when considering childhood immunisation programmes.

Immunisation refusals pose a significant problem for the programme and the control of vaccine preventable diseases (VPDs). Unvaccinated children put those who cannot be vaccinated for medical or other reasons at risk. A higher incidence of VPDs and outbreaks among communities with high level of exemptions in the USA is well documented (Salmon 2006: 436-442; Feikin 2000: 3145-3150). It is reported that the last significant polio outbreak in the USA was amongst communities religiously exempted from mandatory immunisation (Salmon 2001: 289-295).

Another case of misconceived risk which resulted in refusal to immunise occurred in Japan with tragic results. Following media coverage concerning neurological injuries suffered by two children allegedly caused by the DPT vaccine, the public responded with

a refusal to comply with immunisation for pertussis which was a public health mandate. Due to parental refusal, the coverage supplied by immunisation dropped drastically from 1974 to 1976. A pertussis epidemic occurred in 1997 that resulted in an excess of 13, 000 cases, and 41 deaths (Gangarosa 1998).

With the need for public cooperation to make an immunisation programme successful, the role of public education including that of the media cannot be overemphasised. It is essential that strategies be developed for clear, informative and non-sensationalised reporting of public health issues. This requires the cooperation on the part of both the media and the public heath officials. According to Schuchman and Wilkes (1997: 976), media sensationalism comes about by both scientists and reporters failing to appreciate each other's rules of communication resulting in blaming each other for misleading the public. To have an immunisation programme succeed, public health officials must ensure the cooperation of the public. To this end, recognition of a community's cultural, experiential, social, and economic circumstances and the ways in which public health messages are conveyed become paramount factors the ways public cooperation is elicited.

3.4 Principles for making immunisation universal

The decision for making immunisation services universal follows special guidelines which are grounded in the field of public health. These guidelines entail beneficence, non-maleficence and justice principles. WHO has developed a decision making framework which guides decision making and spells out the important considerations before a new vaccine can be introduced into a universal immunisation programme

(WHO 2005). This guide follows a similar framework of ethics for public health and for implementing public health interventions, proposed by Kass (2001:1776-1782). Kass proposed a 6 step framework for ethical analysis of an intended public health program, which covers: 1) the public health goals, 2) effectiveness in achieving the set goals, 3) known and potential burdens, 4) alternative approaches, 5) fair implementation and 6) equitable balancing of burdens and benefits. In this framework, there is an emphasis on fair implementation and ensuring that a programme seeks to minimise societal inequities and at the very least does not exacerbate existing inequities.

This ethics framework for public health is quite similar to the WHO decision making framework for decision making in introducing new vaccines for universal immunisation. According to the WHO framework for universal immunisation there are two major areas to consider: the policy issues and programme issues (WHO 2005). Programme issues although important in assessing the practicality of implementation, are not considered any further in this research. Policy issues are of primary importance and include: disease burden, effectiveness of the intervention, safety of the intervention (vaccine), cost-effectiveness of the vaccine and net impact on the immunisation programme as well as the health sector. Considering the disease burden informs on the assessment of a disease as a public health problem. Included in this analysis is: disease incidence, hospitalisation, mortality and complications. Cost-effectiveness and fiscal impact is a significant area, which is assessed in relation to the many competing health needs. This determines whether a country will be able to afford the intervention. Vaccine safety and effectiveness are addressed in clinical trials and assessed by the National Regulating Authorities (NRA) during licensure. Vaccines have to meet stringent international and local requirements on safety and effectiveness before licensure.

Verweij and Dawson (2004:3122-3126) have suggested a set of ethical principles to guide universal immunisation programmes, based on discussions amongst experts in public health and ethics. The principles suggested by Verweij and Dawson are similar to the two frameworks described above. However, similar to Kass, Verweij have stressed certain elements: that there should be just distribution of benefits and burdens, participation should generally be voluntary unless compulsory vaccination is essential to prevent concrete and serious harm and public trust in the vaccination programme should be honoured and protected.

South Africa uses a similar framework in the decision for introducing new vaccines into the EPI. A detailed process is engaged with the contribution of experts who consider all the issues brought up in the ethical and decision making framework. A group of experts considers these areas, and makes a recommendation to the Department of Health to include a vaccine in the universal programme. (Ngcobo, Cameron submitted for publication SAJEI). Therefore the immunisation programme in this country and many countries that follow WHO guidelines is based on ethical principles for public health programmes.

4. Ethical Basis for Immunisation

4.1 Ethical Theories that Support Immunisation

Utilitarian: Consequence Based Theory

A universal immunisation programme has the primary goal of decreasing the incidence of vaccine preventable diseases (VPDs) by protecting individuals and communities. It is focussed on utility in that it seeks to maximise collective goods. As the utilitarian ethical theory is based on the fundamental principle that an act is right if it produces the best overall results, it forms the ethical basis and justification for public health interventions (Coughlin 2006:16; Beauchamp 1994:55). This reasoning is supported by successful immunisation programmes showing that 1) the universal immunisation programme has shown that it saves lives 2) the saving of lives is a good so 3) the consequences of the action (of universal immunisation) to save lives is a good .

It is simple to understand the moral justification of utility and generally easy to apply. According to this approach we may overlook the rules and maxims advocated by deontologists, rather we seek to only to act towards the production of the greatest amount of utility (happiness, good or pleasure) for the greatest number of people; the maximum benefit for all concerned. This means that in pursuing to maximise the good (the utility) for the greatest number of people, we may trump other considerations such limiting individual rights[8] when it is for majority benefit. In the case of immunisation programmes for example, because the success of the programmes rests in its ability to modify the epidemiology of VPD, it relies on a high level of vaccine coverage (Schoub 2002: 47). So a decision to immunise will weigh heavily on the positive balance for the

[8] As noted earlier, this does not mean that we are insensitive to human rights, rather, societal rights may trump those of the individual, a point I will discuss later.

overall good for society. In this way, we can see the applicability of the principle of utility. Likewise, it must be said, that if society perceives immunisation as a negative, fails to immunise, and a disease epidemic occurs, the consequences of this action will be wrong as the overall consequences are bad for society.[9]

A universal immunisation programme is morally grounded on providing the maximum benefits for the population and individuals. This is not only backed by the expected results of herd immunity but also by the guiding principles in the decision making process on implementation of a universal immunisation programme, including cost-effectiveness. The principles used for decision making on new vaccine introduction for universal immunisation, already discussed are grounded in this ethical approach. Immunisation services based on these principles and the risk-benefit analysis have a strong moral basis grounded on the utilitarian theory.

The application of this theory to the immunisation programme in South Africa is well fitting as the achievements of immunisation in this country are in keeping with the global achievements and include; the interruption of wild poliovirus transmission, tetanus elimination and control of conditions like measles and haemophilus influenzae type b. (Ngcobo 2008: 9-13). These conditions in the past caused a lot of suffering, disability and death.

[9] See earlier reference (Gangarosa 1998), concerning misperceived risk and outcome in a Japanese pertussis epidemic. Also an example of localized outbreaks caused by failure to consider the whole of the community is exemplified in a measles outbreak in the USA (May 2003).

Communitarianism

Immunisation also finds a strong moral basis in communitarianism. Communitarians maintain that acts are right and justifiable depending on: their communal value, the common good, the social goals, traditional practices and cooperative value (Beauchamp 1994: 77). Conventions, traditions and social solidarity are valued by the members of a community. According to communitarians, as long as society values certain practices and believes in the collective benefits of those practices, individuals within a community are morally obliged to such practices. Communitarians will advocate for limiting freedom of individuals for the sake of common good and public interest (Callahan 2002). This may mean that practices valued by society may be enforced. As universal immunisation services are provided for public protection, many communities would be concerned about the devastating effects of infectious diseases and would desire protection, when such protection is available.

Beauchamp and Childress (1994: 82) state that communitarians will recommend laws that will make organ procurement a community project by promulgating the presumed consent laws. Accordingly it would be assumed that individuals and families donate the needed organs of a deceased person, unless they have filed an objection. Based on this reasoning and applying the strong allegiance to community values, it is evident that communitarians should find parents obliged to immunise their children and would be expected to favour laws that make immunisation compulsory.

There is little doubt that most societies in this country value immunisation and its benefits. There are however reported isolated incidents of communities in North West

province and KwaZuluNatal, that have refused to participate in mass immunisation campaigns in the past (personal communication with North West and KwaZuluNatal EPI Provincial Managers, 2007 following the national polio and measles campaign). However, there has been no indication of refusal of routine services.

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The communitarian theory will not support universal immunisation in cases where the whole community is opposed to immunisation, if a majority in a community perceive more harm than benefits. The northern states of Nigeria who had misgivings about the polio vaccine and consequently refused to participate in the polio immunisation campaigns aimed at polio eradication, provide such an example (CDC 2005:873-877). It is worth noting that, when communities have refused immunisation it is not so much because they do not value protection from the targeted diseases but refusal is commonly due to broken trust between the community and the providers of the service, as was the case in Nigeria.

Communitarianism is similar and encompasses a similar notion to the utilitarian approach, as both are directed at public good for a community. However, with the utilitarian approach government officials or outsiders can make the decision about what is good for a community, whereas with communitarianism the value of utility must be appreciated by the community itself.

Daniel Callahan (2002: 169-196) supports the Communitarian approach for public health interventions. He opposes a decision making process based on individual rights, as he maintains:

> "We should enact public policy from a shared consensus about good society, not on the basis of individual rights. Liberal assumptions about state's neutrality should be scrapped and society should be free to implement substantive concept of the good. Biomedicals should use communitarian values to implement or revise social laws and regulations governing the promotion of health, the use of knowledge ….. In each case the question to be asked is: What is most useful to a good society? Not . .. Does it violate autonomy?"

This report maintains this view and concedes that may be the communitarian approach in combining utility and community values provides a stronger moral justification than a pure consequentialist approach. With this approach a public health programme is not only based on utility, which is an important element; but it is perceived to be of value to a society, therefore a public health intervention based on communitarianism should enjoy community support. This will be better achieved if the community is involved in decision making and in setting priorities in public health programmes as suggested by Callahan.

According to communitarianism, the society and the state in an effort to secure societal good should be able to implement laws that safeguard the public good and the environment without being restricted by the individual rights. In South Africa there is limited if any community involvement in decision making on provision of immunisation services, at national level which is responsible for setting policy. There are ongoing efforts at service delivery (facility) level to have Clinic (Facility) Committees. The existence of functioning committees varies widely from area to area. It is doubtful if one can consider their existence to represent meaningful community involvement in service delivery, albeit a significant step.

Both the utilitarian and the communitarian theories bring up an important moral criterion on benefit to society which sets them apart from the other theories. The application of the communitarian theory in our setting will help introduce a procedural requirement of involving the community in decision making. This may be a significant step in that it will address the element of trust and acceptability of a universal immunisation programme, by so doing position EPI strongly against any future adversaries, particularly the anti-vaccination lobbyists.

Kantianism

The deontological ethical theory based on Immanuel Kant's philosophy is one that can be considered to support compliance with universal immunisation services. Immanuel Kant insisted on a categorical imperative that declares certain actions or inactions as necessary. The categorical imperative should guide reasoning and decisions, even if we accept that we may not be able to carry out certain acts (Hill 2000: 227-246). The categorical imperative is differentiated from a hypothetical imperative, where a performance of an action is directed at purpose to achieve specific desired results; "Do A in order to achieve X'. The categorical imperative on the other hand is binding, irrespective of the consequences. It demands an action for its own sake and places an absolute moral demand. Therefore, we should accept a categorical imperative as a sufficient and overriding reason to act in accordance with its demand. Acting in accordance with a categorical imperative does not consider one's desires or personal ends and may very well be in conflict with our interest. (Hill 2000: 236)

Kant further reasoned that we do good because of its intrinsic good, good that is not affected by circumstances neither is it dependent on any condition. He maintained that the ultimate principle of morality must be a moral law that can guide us to the right action under all circumstances. With this he came up with the concept that a moral law should have the property of universalizability. An act that cannot be performed by others with the same moral acceptability cannot be regarded as morally acceptable. (Kant 1785)

> "Act only according to that maxim whereby you can at the same time will that it should become a universal law."

Kant's analysis is that, we should not treat others as means only to our ends but we should treat others as ends in themselves. He based this on the premise that a free will is the source of all rational action and to treat it as a subjective end will deny the possibility of freedom in general. Therefore it would contradict the universal law to claim that a person is merely a means to some end rather than always an end in his/her own self.

When we consider Kant's position on these points and relate that to immunisation it becomes evident that, immunisation is an act that is universalisable, due to the fact that immunisation requires public cooperation to be effective. Therefore opting out of immunisation cannot be a universal act in any community. Dawson constructs a similar argument based on Kant's moral reasoning. He points out that Kant's categorical imperative demands that we think about the implications of our actions on the whole community (Dawson 2007: 175).

According to Kant, we may be morally obliged to conduct certain acts not because of their benefits to anyone, but merely because it is morally required of us; the categorical imperative. The moral requirement that Kantians can be presumed to have imposed on themselves as prescribed by: the categorical imperative, the universality of moral law and to the need to treat humanity not as a means but always as an end, demand that they comply with the universal act of immunising children. The universalizability of immunisation is further substantiated by that Kant insisted that people have a duty not to act by maxims that create inherent or impossible states of natural affairs when we attempt to universalise them (Kant 1785).

Kant insisted that as moral agents and rational agents we have autonomy. The concept of being bound to act according the demands of a categorical imperative is despite Kant's strong rhetoric for individual autonomy. Hill (2000) clarifies that the autonomy advocated by Kant allows one to understand the categorical imperative and the reason behind the imperative. The categorical imperative should be self imposed; it should not be mere compliance with externally exerted pressure. Furthermore, according to Kantianism an act should not be conducted because it is prudent to do so nor because of its utility. This will mean that the autonomy advocated by Kant, does not support acting against the demands of moral maxims. It is the freedom to act within certain laws that one has created for oneself. It means subjecting one to the constraints of the categorical imperative autonomously with the full understanding of the reason of the maxim even if does not serve our interest. Applying Kantianism therefore morally obliges us to immunise our children, if we accept immunisation as a categorical imperative that is universal.

Furthermore, according to this theory we will comply with such a programme with our free will, autonomously understanding that it is not necessarily for our own ends. This means that in countries where immunisation is legally enforced, one will participate because it is morally right to do so, not merely respecting the law. According to Kant, it is not morally praiseworthy to act in accordance with the law, one must act in accordance with a categorical imperative, fully embracing a particular maxim independent of external enforcement. Although it is clear that the Kantian theory should form a strong basis for universal immunisation programme, reports are that Kant was critical of smallpox vaccination (Dawson 2007:175). This however illustrates the limitations of the theories and the poor application of principles by the very people who prescribe them.

4.2 Early Philosopher, John Stuart Mill

The moral reasoning of John Stuart Mill a widely quoted early philosopher, who believed in individual liberty provides a strong moral justification for a universal immunisation programme. Of direct relevance is Mill's "harm to others principle". According to Mill the sole purpose for which power can be exercised upon any member of a civilised society, is to prevent harm to others. This, he referred to as the "harm principle / harm to others principle", the principle that is supposed to govern the dealings of society with individuals (John Stuart Mill 1869).

Bayer (2004) indicates that public health interventions have been justified with the invocation of the harm principle, which was first enunciated by John Stuart Mill. The harm principle therefore, provides the standard for judging liberty limiting acts of governments. Bayer goes on to say that limitations of individual rights in the face of public health threats are firmly supported by legal tradition and ethics. To this end the consequences of lost herd immunity pose a serious threat of "harm to others". Furthermore, in the case of refusal to immunise a decision is taken on behalf of children, who either cannot or have not consented to this imposed harm on themselves as well as to others who may be affected. [10] May (2005) maintains that the threat of harm to others will significantly alter the autonomy based considerations, as restricting autonomy rights is a necessary component of a liberal constitutional system that seeks to balance the interest of diverse individuals who have a plurality of values.

[10] The significance of harm to others posed by opting out of immunisation is highlighted by a number of writers particularly with reference to outbreaks where coverage is low and amongst those eligible for exemption from mandatory immunisation Dawson 2007; May 2005; Bradley 1999, Gangarosa 1998 and Freed 1996.

Mill (1869) on Liberty maintained that individual rights and actions cannot be considered independent of their utility.

> "I regard utility as the ultimate appeal on all ethical questions; but it must be utility in the largest sense grounded on permanent interest of man as a progressive being. Those interests, will authorize the subjection of individual spontaneity to external control in respect to those acts which concern the interest of other people. If anyone does an act hurtful to others there is a *prima facie* case for punishing him by law, or where legal penalties are not safely applicable by general disapprobation. There are also many positive acts for the benefit of others, which he may be rightfully compelled to perform; such as … to bear his fair share in the common defence, or any other joint work necessary for the society of which he enjoys the protection…"

The interpretation of Mill's reasoning has significant moral implications for participation in a universal immunisation programme. He points that acts may be punishable or forbidden if they cause harm to others. He refers to positive acts for the benefits of others which an individual may be rightfully compelled to perform if he enjoys that protection, as quoted above. This accordingly, applies not only to action but to his inaction as well, as one may cause evil to others not only by his action but also by his inaction. In either case he is justly accountable for the injury that may result. (Mill, 1869)[11]

Therefore one cannot use individual liberty as a defence for opting out of an intervention programme that has clear benefits for society that all enjoy. In the case of immunisation opting out may eventually lead to harm to society as a result of outbreaks and human suffering that follows. This has specific relevance for many diseases targeted by the immunisation programme in South Africa, which have not been eradicated, like measles.

[11] Mill's position on harm to others by one's action or inaction is despite his strong rhetoric for individual liberty and the importance Mill attached to individual freedom.

Mill in his work, "Of the Limits to the Authority of Society over Individual", considers the issue of relationship of society and individuals that such a relationship is not based on a contract and further concedes that it will serve no purpose to create such a contract. However, the point is clear that everyone who receives protection from society has to pay it back somehow:

> "Even though society is not founded on a contract and there will be no good purpose answered by inventing a contract in order to deduce social obligations from it, everyone who receives the protection of society owes a return to society for the benefit. The fact of living in society makes it unavoidable that each member of society is bound to observe a certain line of conduct towards the rest. ….. This conduct consists of not injuring the interest of another…… each person bearing his share (to be fixed on some equitable principle) on the labours and sacrifices incurred for defending the society or its members from molestation and injury. These conditions, society is justified in enforcing at all costs to those who endeavour withholding fulfilment. Conduct may not just be hurtful to others, it may be lacking in consideration of the welfare of others. Whenever there is a definite damage or a definite risk of damage, the case is taken out of the classification of liberty and placed in that of morality or law."

This is one of the most convincing analysis on moral justification to comply with the demands of a public health programme. It highlights that individuals owe society for the share individuals enjoy in common defence and for this he must in return play his part for the good of society. Opting out of a public health programme whilst enjoying the benefits is directly attacked. Mill concurs with communitarianism in that society can enact legislation to demand actions that will promote the interest of society. This moral reasoning provides the basis for making immunisation compulsory. Mills reasoning encompasses the necessary dimensions for immunisation justification as it combines utility and communitarians; relates to utility of acts on others, whilst grounded on liberty.

4.3 Principle Based Approach

It is compelling to consider the Principlist approach, "Georgetown model" and see how the immunisation programme in this country could be evaluated based on the well known 4 principles of: beneficence, non-maleficence, autonomy and justice outlined by Beauchamp and Childress (2004).

The principle of beneficence requires that a practice should benefit recipients. For public health programmes, beneficence requires that society should benefit. Immunisation services fulfil this principle as extensively outlined. The benefits conferred by immunisation for individuals are so strong that, the practice is considered to be in the best interest of the child. In cases where parents have refused to immunise their children, courts have used this concept of the *best interest of the child* to demand that children be immunised. [12] This also applies to refusal of life saving treatment based on religious beliefs. [13] Furthermore, the decision making process for universal immunisation is grounded in the principle of beneficence in that the focus is on utility and thus on benefits to individuals and society.

The principle of non-maleficence is considered and applied in the decision making process for universal immunisation and is covered through safety consideration which is an important element of this process. Stringent licensure requirements are in place for

[12] In the US courts have not hesitated to reject religious objections to vaccination or to over rule parents decision to further the interest of the child based on *Parens Patriae*. Malone 2003 ; Cude v State, 237 Ark 927 (1964); Prince v. Commonwealth of Massachussets, 321 U.S. 158 (1944) and Wright v De Witt School District , 238 ark 906 (1965). Prince's case is that of Jehova's Witness,

[13] This is the case with Jehova's Witness followers, and parents may refuse blood transfusion on religious grounds. In 2005, Judge W. Seriti granted doctors at Pretoria Academic Hospital a court order to transfuse a month old baby whose life was perceived to be at risk (Zelda Venter 2005)

vaccines generally in all countries. South Africa has additional local safety requirements by the Medicines Control Council (MCC), highlighted elsewhere in this report. This requirement forms part of fulfilling the non-maleficence principle. However, the principle of non-maleficence can be further fulfilled by establishing a compensation system for those who are affected by severe adverse events following immunisation with grave consequences like disability. This is discussed further under the specific challenges for South Africa.

The rendering of the immunisation services is based on the principle of justice. All children in the targeted age group, below 5 years are the beneficiaries of the programme; irrespective of where they come from, race, religion or socioeconomic circumstances. The provision of free immunisation services further fulfils the principle of justice. No one is excluded from immunisation services, save only for the limitations of infrastructure and resources that render access to health services difficult in some disadvantaged communities.[14] Furthermore the immunisation programme is structured such that no specific groups or individuals are made to bear an unequal burden in terms of risk or any other foreseeable burden; therefore there is a just distribution of burdens.

The principle of autonomy is also respected in that participation in immunisation is voluntary in this country. Where there has been resistance, negotiations and developing understanding has overcome initial obstacles. Refusal by some communities to participate during immunisation campaigns is addressed by negotiations and providing clarity and information on the programme. However, it is well accepted that principles

[14] There are ongoing efforts and community collaboration allow for means to be established for health services to reach such communities. Remote communities are reached through the use of mobile services.

will often be in conflict and when there is a conflict of principles the goals of the programme have to be overriding. Quite often one principle will override the other/s as it commonly happens in clinical medicine.

4.4 Theories that Oppose Universal Immunisation

Liberty: The Rights Based Approach

The Right Based approach and the theory of liberty bear an interesting and apparently strong stand against public health programmes, particularly enforced programmes. The origin of rights and the concepts of liberty were to provide protection of individuals from the state power which at times could be unlimited and provide protection against unequal treatment, intolerance, arbitrary invasion of privacy and help ensure protection of life, expression and property.[15] Rights and the concept of autonomy formed the basis for bioethics due to initial focus of bioethics on the abuse of medical research subjects, doctor – patient relationship which was originally paternalistic and the development of high technology medicine (Bayer 2004; Callahan 2002). However depending on the basis of one's argument, rights may also be used to justify the provision of immunisation services including compulsory immunisation.

Liberals will argue that parents have a right to autonomy and to have their decisions about the health care of their children respected. Furthermore Parental rights to decision making for their children and the duty of care for their children is well acknowledged. Imposing universal immunisation and services offered without provision of adequate information may be seen as violating parental rights to this freedom of will.

[15] The movement for human rights gained more recognition following the atrocities of the Second World War. In 1948 the United Nations adopted the Universal Declaration of Human rights. This was later followed by 2 main treaties: The International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights. (Int. Federation of the Red Cross 1999)

Parental autonomy should be considered in tandem with its consequences, of loss of herd immunity which may pose a serious threat of "**harm to others**".[16] There are two groups that may be exposed to harm if the parents decide not to immunise their children: their own children and other children in the community. The application of the harm principle will apply to both groups and has significant bearing on the right to autonomy. According to May & Ross (ibid), the threat of harm to others will significantly alter the autonomy based considerations. They point out that the "harm principle" forms the basis for restricting autonomy in liberal societies. Restricting autonomy rights is a necessary component of a liberal constitutional system that seeks to balance the interest of diverse individuals who have a plurality of values.

Furthermore, when parents fail to provide reasonable adequate care for their children, they relinquish the right to rear and make decisions for their children (Malone, 2003). Refusal to have one's children immunised may very well amount to this kind of parental failure to provide adequate care for one's child which may result in harm to one's own children. This is similar to other situations where parents fail to act in the best interest of their children, like the practice of Jehovah's Witness which extends parental refusal for their children to have blood transfusion. Whilst the law regards parents as the legitimate decision makers on matters that relate to their children, the law will not hesitate to take action in the best interest of the child, should courts be convinced that the parents are failing in their duties. [17]

[16] The concept and effects of harm to others as it relates to children who cannot take such decisions has been discussed.
[17] See reference 12 and 13 above.

The liberals will maintain that the public and individuals have a right to be informed about the benefits; the risks involved so as to give their informed consent and may demand that an acceptable level of privacy be provided. This will mean that when services are provided the information on the rights of parents to refuse immunisation will be provided at the same level of emphasis as the information on benefits.

Governments have a responsibility to fulfil this duty. Resource limitations in South Africa and other developing countries do not allow the provision of services that will satisfy this kind of standard. Clements and Ratzan (2003) appreciate these limitations. They indicate that the constraints lead to limited disclosure of information, particularly where literacy levels are low and the danger of the infectious diseases prevented by vaccination is much higher than the risk of the vaccines. Under such circumstances the priority should be to offer protection than to dwell on the rights of individuals to full information. This is in contrast to areas where a condition like measles is rare, resources are adequate, the parents in this setting will require much wider discussion and information.

Concerns have been raised about the quality of information provided by the immunisation programme and the tendency to overstate the benefits whilst down playing the risks (Paul 2005). Although information provided may be considered incomplete, on the other hand, providing too much information in our setting may amount to truth dumping, which could have undesirable consequences. Information to a parent about the 1 in a million encephalitis cases associated with measles vaccine, is likely to end up with an alarmed parent who will not have her child immunised. Callahan (2002), states:

> "Vaccines are as safe as humans can presently make them. Yet in any health intervention, some level of uncertainty will always remain. It is not easy to present this concept accurately and ethically to the public without driving the impression that vaccinations should be avoided."

The main question is 'How much information on risk and side effects should be shared with parents and caregivers?" Specific country circumstances are of relevance. Whilst parents and care givers should be given adequate information for decision making, it still has to be established "How much is adequate?" The consequences of providing too much information as well as the practicality of providing detailed information should be considered. There is a need to strike a balance between the public's right to know, the duty of the government to a needed immunisation programme and the obligation of individual health professionals to inform.

The Rights Based approach should not only apply to opting out of interventions, children have rights to intervention programmes aimed at reducing morbidity and mortality. Public health programmes have over the years adopted the right based approach and this move has been supported by the international agencies like UNICEF. The Application of the rights in this context is in sharp contrast to using rights to disclaim the ethical position of universal immunisation. The Rights Based approach to providing immunisation services maintains that "Every child has a right to immunisation." This approach is more concerned about the number of children who are not reached by immunisation services and are denied their rights protection (Jonsson 2003: 31-43).

When properly analysed the Rights Based approach provides a strong basis to advocate for quality services of an acceptable ethical standard. Whilst this may not be realised overnight, these areas should be addressed so that services progressively approach this

standard. It should be highlighted that in our setting it may be misleading to consider such areas as primarily ethical issues rather than as issues that relate to constraints in service delivery.

Kantianism

Whilst Kantianism as considered earlier should provide a strong basis for universal immunisation services, others may look at this theory as providing a basis for opting out. Kantianism stresses individual autonomy, and can be viewed to support the right of parents to make decisions on the matters of their children. Some may be inclined to interpret this to mean that, autonomy should give individuals a free will to opt out; if the autonomy is not fully understood as being subject to a categorical imperative.

The practical setting in which the services are offered may cause misinterpretation. Kantians may conclude that the immunisation service fails to abide by the categorical imperative of providing full information. However, considering the universal nature of the immunisation, a core element of a moral action according to this theory, the limitations of health services cannot provide ground for actions that cannot be universalisable.

It is doubtful that Kantians will be concerned about risk analysis and cost-effectiveness, as they are not concerned about the consequences. It is interesting to consider the position of Kantians when they consider the “best interest of a child”. The principle of justice and considering the best interest of the child may be another dimension in the rules and categorical imperatives that Kantians should consider. This aspect should further tip the scale for Kantanians in favour of universal immunisation.

There may be a conflict of maxims: the respect for parental decisions and the best interest of the child. However, the overriding maxim should be one that is universalisable and should treat people as ends in themselves. The conflict of rules or what can be considered categorical imperatives in such a case, demonstrates the limitations of this theory, particularly in relation to public health programmes.

5. Repudiation of Ethical Objections to Immunisation

This chapter looks at the main arguments used to disclaim the ethical basis of a universal immunisation programme. The aim is to analyse and refute such claims. Some concepts will resurface as they are considered in detail in the process of repudiating the arguments of ethical objections to a universal immunisation programme.

5.1 The Nature of Immunisation and Moral Conflicts

Apart from the setting in which immunisation services are offered, the intrinsic factors in the nature of the immunisation programme bring up major moral and legal conflicts. The intrinsic factors include the following: immunisation is given to healthy individuals with the aim of preventing a disease, which may or may not affect that particular individual immunised; the benefits of immunisation are not just for the individual but are also for the community – due to herd immunity that develops when a large number of individuals are immunised; the herd immunity benefits include protection of individuals who are not vaccinated as well as those who were vaccinated but did not develop the desired immune response. The main objection presented by some is that universal immunisation infringes on individual liberty and specifically compulsory immunisation violates individual rights afforded to individuals by the constitution. To this end the programme is considered paternalistic and coercive.

Further complicating matters is that immunisation is not completely without risk, there is a risk of side effects from the vaccines. The more common side effects are generally minor, like local swelling and pain at the injection site, fever and irritability. Serious side effects like encephalopathy may occur on very rare occasions. Furthermore it cannot be

predicted with any level of certainty, as to who will get the side effects after exactly how many doses of a vaccine. We do not know for sure what the exact figures and incidence of side effects are; quite often figures are given as a range which varies widely from one setting to another. Similarly we cannot be sure at what level of population immunity an outbreak of say measles will occur. [18]

The following section considers each point of the argument raised and shows that there is strong moral and ethical justification for universal immunisation. The key elements of the argument presented by Dawson (2004) are used. Key elements:

a) Preventative public health programmes like immunisation are performed upon asymptomatic individuals,
b) A public health intervention like immunisation will carry some risk of harm,
c) Risks are carried by individuals yet benefits lie at the level of populations

The conclusion: Such prevention programmes are unethical, given the distribution of risk and benefits.

5.2 Risk and Benefit for Healthy individuals

Following on the key elements highlighted above, one of the arguments brought up by those opposed to universal immunisation is that healthy individuals, who do not have a disease, take personal risk for a condition that may not affect them. Dawson refers to this as the "prevention paradox"(Dawson 2004). According to this argument, healthy individuals are subjected to an unjustifiable level of risk from a vaccine which aims to

[18] The uncertainty that affects public health programmes, which relates to the uncertainty of science has been acknowledged by writers, Callahan (2002) and Blum (2006: 273-281).

prevent a disease that has a low risk, and even if one were to get the infection it is argued, it is not serious (Clements 2003). The other area of concern brought up is that healthy individuals cannot be expected to tolerate risk from immunisation in the same way one tolerates risk from treatment of a condition that has affected that individual.

The argument presented is: One cannot tell who amongst the immunised, would have been infected and who will be protected and thus receive the benefit of immunisation, yet harm or inconvenience is borne by all. Whilst any individuals may be harmed, the benefits will be for a very few unidentifiable individuals. So, according to this argument, benefits are few and distant, even likely to be nonexistent; whilst any potential of risk clearly exists; the "prevention paradox". [19]

Refuting this argument

Anyone who argues along these lines is arguing from the safety net of the current levels of protection from VPDs enjoyed by many countries based on high levels of population immunity. In South Africa such an argument cannot be valid. Even in developed countries such an argument may not be valid. During the years 2003 -2005, South Africa experienced a huge measles outbreak, which affected five of the 9 provinces. The annual number of confirmed measles cases over these 3 years ranged from 251 to over 830 cases. Prior to this South Africa had reached a stage where the annual number of confirmed measles cases was less than 60 with an average 29-30 confirmed cases per year (Ngcobo, 2008). Based on the level of measles control the country had reached prior to this outbreak through the implementation of WHO recommended strategies,

[19] As pointed out by Dawson on reflection of Rose's argument (Dawson 2004)

South Africa was considered to have eliminated measles (Biellik 2002:1564-1568). The propagated measles outbreak was associated with significant morbidity, a number of hospital admissions and some deaths. [20]

Similarly, the experiences of other countries like Japan, UK, US and Russia (already cited) further illustrate that such outbreaks do occur and can result in significant setbacks, which may take a country years to recover. In countries where the level of HIV infection is high, the health consequences of a measles outbreak are much more serious with a much higher case fatality ratio (Moss 2003).

The point to bear in mind is that, the purpose of a prevention programme is to preserve a healthy state of individuals; otherwise anyone who is healthy today may not be healthy tomorrow unless certain measures have been taken to preserve that healthy state. It should be stressed that the risk from infections like measles and pertussis, which have not been eradicated and are easily transmissible by droplet spread remains significant. This applies to developing and developed countries as seen with the measles outbreak indicated above. This is true even in countries where the current incidence of such infections is low. The risk of outbreaks from importations and re-emergence of local strains become a threat when the level of population immunity drops. Therefore element (a) above: the programme is performed on healthy individuals, who are presumed to face little risk from the disease targeted by immunisation, is not valid.

[20] The actual number of deaths could not be determined due to the compounding factors of HIV and AIDS infection.

Furthermore, to say that we cannot predict the individuals who will be affected by a disease and consequently be the main beneficiaries of immunisation does not carry weight. It is well documented that as population immunity drops disease outbreaks occur. Notwithstanding the fact that measles will practically affect all those exposed who are not immune (Christie 1980:357-386).

Let us consider element b: Immunisation will carry some risk of harm. Implicit in this argument is the assumption that the risk from immunisation is higher than the risk of the disease it is meant to prevent. In the preceding paragraphs we have already addressed the fact that conditions like measles cannot be said to carry a low level of risk, certainly not in this country. Let us now consider the risk carried by immunisation. Whilst it is well accepted that vaccines carry a level of risk like any medical intervention, it should be pointed out that vaccines are safe. They are as safe as they can be currently manufactured and undergo stringent safety verification before licensure. To put the matter into perspective; the risk of encephalitis is one in a million doses of measles vaccine, yet the risk of encephalitis from measles infection is 1 to 2 per 1, 000 measles cases, which is 100 times higher (Kimmel 2002: 2113-20; Patja 2000: 1127-1134). Other serious complications of measles like subacute sclerosing panencephalitis carry similar ratios, apart from that there are no deaths conclusively associated with the measles vaccine in well infants. It is evident that the risk from this disease is much higher and carries much more serious health consequences.

Based on the empirical evidence of the risk of a disease compared to the risk of a vaccine, the argument that the risk from immunisation is too high compared to the disease itself, cannot be based on risk–benefit analysis using empirical evidence of

country experiences of outbreaks following a decline in coverage levels. One cannot claim that a condition like measles is generally not serious. Certainly not in our setting where many are at high risk including those who are: immuno-compromised, under nourished and may have underlying conditions. Measles carries significant morbidity and mortality particularly in such high risk groups.[21] In South Africa with the high incidence of HIV/AIDS, a high prevalence of under nutrition, measles is indeed a serious condition.

The point of a risk of a disease versus risk of a vaccine becomes even more significant when we consider that everybody could wish to avoid immunisation on these grounds. Every parent could say; “I do not have to vaccinate my child it is only for the good of the community, it will not benefit my child, who will run the risk of the vaccine.” what would be the outcome in terms of outbreaks and re-emergence of previously controlled diseases. If this were the standpoint of all parents, the whole scenario changes. Such arguments are brought up in the comfort of knowing that a large majority still vaccinate their children, so an objection is brought up whilst enjoying the safety of herd protection. This is a free riders argument, based on an action that is not universalisable.

The argument, of free riders is supported by Dawson (2007) on: “The Existence of Herd Protection and the No Additional Benefit Argument.” Dawson argues that where herd protection exists there is no harm done to others (third parties), therefore an individual’s decision not to vaccinate does not harm anyone. His argument is that, where there is no herd protection individuals have a moral obligation to vaccinate. However he reasons that where there is already herd protection which he acknowledges as a public good,

[21] A high level of morbidity and mortality associated with measles is seen in developing countries (Christie 1980).

established by the actions of others and everyone receives a share of it, in such cases an individual may opt out if he wants to. He claims that there is no additional benefit to others and vaccinating against one's inclination in such a situation is a futile action of conformity. The points already discussed clearly dismiss such an argument. It's a free riders argument that is permissible for a few. An *exceptionist's* argument that hopes that one is an exception and no one else does the same. Furthermore it does not consider that a state of herd immunity is not static it changes all the time, particularly when some people eligible for immunisation prefer to opt out. The point is, "when will one know that so many of us have opted out to a level where herd immunity is lost, one must now be immunised?" What measure could be used to find this point in the level of immunity?

5.3 Individual Protection versus Herd Protection

In this section we will consider the third element (c): Risks are carried by individuals, yet benefits lie at the level of populations. Dawson (2004) on the prevention problem has presented a strong argument that refutes this element. This element of the argument (c) may be considered strong based on the claim that immunisation benefits the public whilst there is little individual benefit and the individual bears the risk of harm. Such an argument may create resentment amongst the public and may be a stronghold for those who promote liberty, who may be intent on opposing public health efforts aimed at benefiting society. Their concern is that individual benefit is small and even uncertain. This report disputes that.

Whilst immunisation gives the public benefits of herd protection, immunisation also protects a large percentage of individuals immunised (accepting that vaccines are not

100% efficacious). The fact is those who are vaccinated are protected from the targeted disease. The immunity generated by vaccination primarily protects the individual; it is only when an aggregated large number of immunised individuals at a certain percentage that herd protection results. Therefore, there can be no herd immunity without individual immunity. Herd immunity is a secondary benefit. Dawson (2004) highlights that, some individuals benefit and (this report adds) a significant majority are protected if one considers the risk level already discussed. Individual protection is a direct benefit that should not be overlooked.

The fact that benefits and impact of a public health programme are measured at population level may cloud the point of individual benefit. Dawson maintains that, although we cannot identify the individuals in advance who will get the infection and thus be direct beneficiaries, individuals still enjoy protection. The response to this point is, “It is not necessary to identify such individuals.” This is a share that each person has in the existence of herd protection as a public good [22] This point becomes clear if we consider measles outbreak in a virgin population, which affects everyone who is not immune as already discussed (Christie, 1980). Even if we could identify such individuals, this would be a futile impractical exercise that would defeat the major goals of immunisation, like disease eradication.

Considering that immunisation provides herd protection which results in the interruption of disease transmission, individuals and communities benefit. Individuals should acknowledge this protection from herd immunity, seeing that it is individuals who contract diseases and fall sick.

[22] Dawson points out the un-excludable goods individuals enjoy, citing Klosko. (2004)

5.4 Social Contract

This section claims that based on the public good of herd protection conferred by immunisation, individuals have an obligation to immunise their children. The utilitarian theory, communitarian theory, casuistry, and the harm to others principle all provide a strong moral basis for parents to immunise their children. This moral obligation is so strong that it has been referred to as a *"social contract*" (Freed 1996). The social contract means that there is an obligation on all members of society to have their children immunised as this will result in herd immunity, which will protect those children who cannot be immunised for medical reasons, those who are too young to receive immunisation and those who experience vaccine failures.

The social contract exists because individuals have a responsibility to play their roles which result in protection of others. The point here is, there are members in a community who are willing to be immunised but cannot be due to constraints beyond their influence. There are infections which affect and may have deadly consequences in the non targeted group. Vaccination of the targeted group results in protection of all including the non-targeted that may be saved from death. Examples include immunisation against pertussis, rubella and influenza. Therefore, immunisation may have an altruistic element (Vernon 2003). All these three infections can either result in death in the non targeted group or result in severe malformations of foetuses due to Congenital Rubella Syndrome. Vaccination against influenza may be mainly directed at school going children but also protects the elderly through herd immunity, who are more likely to succumb to the infection.

The moral reasoning of John Stuart Mill, discussed earlier, brings clarity on understanding the relationship that individuals have with society. Mill strongly protected individual freedom and rights, but when it came to utility of one's actions, Mill considered utility to be the main determinant on which to judge one's actions. Mill points out that we accept that individuals do not have to feel connected or to have a contract with other members of their community. However, he stressed that individuals have a moral obligation to contribute to the welfare of their society from which they reap benefits. The point that people may not feel connected to other members of the community and therefore feel they do not have to make sacrifice for them, has also been pointed out by other writers. (Blum 2006; Bayer 2004) Nevertheless, this does not prelude individual's obligation to participate in a programme like immunisation that benefits society.

Participation in a public health programme may result in small benefits to individuals. What amounts to mere inconvenience at individual level may have huge implications and benefits at population level (Brayer 2004). Immunisation is a good example, in that the individuals may not value protection from immunisation yet at population level it produces significant benefits. What may seem an inconvenience at individual level, taking a child for immunisation, has a significant impact at population level; that of herd immunity, disease elimination and even eradication. Most will agree that individuals are morally obliged to perform acts that may be an inconvenience and perceived to be of little benefit to them, but which carry significant public good

The implications of a Social Contract in relation to the 2003-05 measles outbreak in South Africa and its consequences on the non-targeted age groups are considered briefly. Measles immunisation is administered to children at the age of 9 months and a

repeat dose at 18months, in keeping with WHO recommendations for developing countries. Children between birth and 9 months of age are presumed to be protected by maternal antibodies. However the level of natural immunity and that of antibodies amongst women of child bearing is low considering that measles has been fairly under control in South Africa and the previous epidemic was in 1992. This means that many children below the age of nine months are not adequately protected by maternal antibodies. Furthermore, if these children are HIV infected their level of susceptibility to infections including measles is high. Similarly children who are above 9 months who might have received measles may not have adequately responded due to the fact that the vaccine is not 100% efficacious and the high levels of HIV/AIDS infection in this country which interferes with serological response to measles vaccines complicates the picture further. [23]These factors point to a large pool of children who are not protected from measles either because of their age, too young to be vaccinated or they were vaccinated but did not mount an adequate immune response required for protection. Further compounding the issue is that this group of unprotected children are by virtue of their age and by their HIV/AIDS status much more likely to suffer severe complications from measles infection with high levels of morbidity and death.

The 2003 – 2005 measles outbreak illustrated some of these complications quite well. There were a number of confirmed cases during the outbreak that were below 9 months. Deaths were reported amongst the below 9 months age group at a higher rate than in the age group of children targeted for routine immunisation, the 9 months to 5 years (DOH Report Measles Outbreak, 2003-2005). It was difficult to attribute deaths to

[23] Placental transfer of maternal antibodies including antibodies to measles may be impaired in HIV infected women (Moss 2003:61-70).

measles due to cases that had underlying infections/ conditions like HIV/ AIDS. This illustrates that once co-infected the effects of measles are severe. There were also confirmed measles cases amongst adults over the age of 18 years, who are much older than the targeted age group. Adults suffered affected severe measles outbreak infections and a few deaths were reported in those with underlying HIV/AIDS.

The setting in South Africa with underlying endemic infections like HIV/AIDS, malnutrition place an obligation on all members of society to ensure high levels of population immunity that will prevent disease transmission and help protect others who may be more vulnerable. The experience of the 2003-2005 measles outbreak, certainly points to a *social contract* in our setting to immunise children. It may be that complications that arise, (like the high level of morbidity in the non targeted group) some of which are only understood later in the disease evolution, herd immunity may end up protecting the adults who refuse to have their children immunised.

It is those actions which are considered small, insignificant or inconvenience by individuals that will have the collective effect of producing serious consequences at population level and may lead to disaster at national level causing irreversible harm, suffering and death. The question is: Could it be demanding too much of individuals to immunise children for their own protection and help society prevent such setbacks?

6. Group Refusal of Immunisation Services

In this section refusal of immunisation services by a community that takes a joint decision not to immunise their children is considered. Group refusal here, refers to community refusal; it does not refer or include a group of anti-vaccination lobbyist that actively work to discourage communities and individuals not to immunise their children.

Refusal by communities to have their children immunise pose some ethical challenges which are distinct from individual refusal. In a case where a community refuses immunisation services, the understanding is that the majority in the community is opposed to immunisation and thus the decision affects all members in that community. The application of communitarianism in this case binds individuals to a community decision not to immunise children. A community leader either: political, traditional or religious expresses the wish of the community not to participate in the services offered. A community decision like this should be respected and a government has to engage in negotiations and activities aimed at convincing the group to accept the offered services.

There are a few examples of such group refusal, which include the northern states of Nigeria and a local Shona community in North West province, which has on a couple of occasions refused to participate in mass immunisation campaigns conducted all over the country (NDOH, 2004 and 2000 National Campaign Reports). We will consider closely the experience with the northern states of Nigeria as this had far reaching consequences.

Nigeria is the only country in Africa which remains endemic of wild poliovirus (wpv) transmission. Within Nigeria the northern states constitute the last reservoir of wpv in Africa (WHO 2006). Nigeria and India have over the last 6-8 years been the largest reservoir of wpv cases globally. During 2003 to 2005 the Global Polio Eradication Initiative faced significant challenges in Nigeria, when certain northern states of: Kano, Kaduna and Zamfara suspended polio supplementary immunisation activities (SIAs) because of concerns regarding vaccine safety. Kano is one of the most highly populated states in the north of Nigeria with a population of about 7 million people. Kano suspended supplementary immunisation services from April 2003 to July 2004 (CDC 2005) .

The suspension of immunisation activities had serious consequences, as manifested by the sharp increase of wpv cases within in the country from 202 cases in 2002 to 782 cases in 2004. Apart from the total increase in the number of cases, the number of states reporting at least one case of wpv rose from 41% in 2003 to 80% in 2004. There was spread of wpv to a number of states within Nigeria which were previously polio free. Furthermore, the wild poliovirus resurgence in Nigeria led to the spread of wpv cases to 18 other countries including three countries outside Africa. The countries which experienced importations of wpv from Nigeria had been polio free for 1 year or more.

In the case of the northern states of Nigeria, the communities took the decision not to participate in the immunisation activities based on their belief that the polio vaccine was not safe. The community decision was taken with apparent support of political leaders (governors) of these states, who presented the decision to the federal government. The governors of these states again played a significant role in reversing the suspension of

immunisation activities as they helped to convince the communities to accept immunisation services, thus immunisation activities resumed later in 2004.

This incident of community refusal of immunisation services in Nigeria proved to be a major setback for the Global Polio Eradication Initiative; affecting many countries in the continent as well as countries outside Africa like Indonesia and Yemen. It left a large number of children in Nigeria and in many other countries maimed by the poliovirus which originated in Nigeria. Many of those affected may never understand the reasons for the suspension of essential health services, but the disability brought on by that decision is part of their lives. The fact that they had nothing to do with the decision and there was no way they themselves nor their parents could have contributed to the decision, changes nothing as they still bear the consequences. It matters not that such consequences were not intended by the people of the northern states of Nigeria.

It is important to point out that when communities refuse to participate in a public health intervention programme as it happened in Nigeria, the underlying reason is usually lack of trust in authorities; the government and or its partners. Refusal to participate in immunisation services in Nigeria is one classical example as it is reported that the community had suspicions about the motivation of the public officials and rumoured that the vaccine was associated with HIV infection and was contaminated with steroids to cause infertility and thus not safe (Pallansch, 2006). Once the issues of trust were addressed and negotiations undertaken with the different community leaders the issues were clarified, misconceptions addressed and immunisation activities were resumed.

Such decisions bring up serious ethical questions as adults take decisions on behalf of children. Furthermore, in almost all cases of group decisions there will be those who do not share the group concerns and were more worried about the safety and the protection of their children from the disease. In such a situation such people normally have little alternative as failure to comply with the group decision may almost certainly lead to attacks by other members of the community, which may have deadly consequences.

Nevertheless, such incidents bring up the important issues of trust and the ethical obligation of the health officials to ensure meaningful participation of community representatives in decision making on immunisation services and for the programme to provide adequate information on the risks associated with the vaccines (Vernon, 2003). This will result in an appropriately informed public on service delivery issues, like planned activities and will give a sense of ownership for the programme. The refusal of communities in Nigeria to participate in immunisation services point to this gap.

It is evident that in such a situation legal enforcement of immunisation services would not work, if anything it could make matters worse. Legal enforcement in such a situation may bring up resentment by communities and complete breakdown of trust in government programmes irrespective of how well intended.

7. The Specific Ethical Challenges of EPI-SA

7.1 Immunisation Policy and the setting

In South Africa routine immunisation services are offered as part of the essential package of Primary Health Care through the Expanded Programme on Immunisation (EPI), free of charge in public health facilities. The programme is delivered in line with the global strategies and policies of the World Health Organisation (WHO). Based on this, the Expanded Programme on Immunisation in South Africa (EPI-SA) implemented WHO recommended disease eradication and elimination strategies which include: conducting mass immunisation campaigns at 3-4 year intervals, targeted disease surveillance and putting efforts into increasing routine coverage. These strategies are aimed at eradication and control of vaccine preventable diseases (VPDs) like polio, measles and tetanus.

In keeping with the achievements of the immunisation programme in the control of VPDs in developed and many developing countries, the EPI –SA has made significant achievements in the control of VPDs in the last decade. The incidence of measles has dropped from an average of 10 000 to 15 000 cases per year between 1990 and 1997 to an average of less than 100 laboratory confirmed measles cases per year between 2000 and 2006; with 830 laboratory confirmed measles cases per year during the worst outbreak. It should however be highlighted that prior to 1998 all clinical cases of measles were presumed to be true measles. Since 1998 when case based surveillance was instituted, laboratory testing is conducted for all suspected cases, and thus there are confirmed and suspected measles cases (Ngcobo 2008).

Similarly the incidence of Haemophilus Influenzae type b has been markedly reduced, neonatal tetanus has been eliminated and the last case of laboratory confirmed wild poliovirus was reported in 1989. Yet between 1980 and 1988 the number of poliomyelitis cases in South Africa ranged from 25 to 481; with the highest incidence during polio outbreaks of 174 and 481 in 1988 and 1982 respectively (Department of National Health and Population Development, South Africa 1990).

Despite the achievements, the immunisation programme faces challenges similar to other Primary Health Care Programmes. These challenges include: staff shortages, low and poor level of supervision, limited information offered on services provided and other constraints. Jackie Smith (2007) reported a national clinic supervision rate of 44% (defined as the percentage of clinics and Community Health Centres that had at least one supervisory visit per month) for 2006/7. Furthermore, of the 53 districts only 3 had a supervision rate of more than 80% (Smith 2007: 31-46). It is in this setting with such constraints that immunisation services are offered. This raises other ethical challenges which are additional to ethical challenges inherent in the programme.

The ethical framework which encompasses: utility & beneficence, justice in the form of just distribution of burdens and benefits as well as safety, discussed earlier are considered at policy development level. Therefore at the level of health care worker and patient interaction there are three main ethical areas that apply during an immunisation session: confidentiality & privacy, disclosure and informed consent. In medicine the respect for autonomy is expressed through informed consent and has come to be accepted as a necessary requirement that helps to define an acceptable ethical practice in medicine (Paul 2005: 393-406). Parents normally give consent for medical

interventions on their children. For consent to be informed and meaningful adequate information should be given to a patient, to allow a parent to make an informed decision. Information shared should include full disclosure of any risks associated with a proposed intervention. However there is lack of agreement as to what constitutes adequate disclosure and the amount of information that should be shared with patients.

It has been argued that in many settings limited information is offered by the immunisation services, where offered the risks associated with vaccines are understated or minimised. Thus the immunisation programme may be considered coercive, misleading and to violate the parental rights to autonomy as in most settings no proper effort is directed at obtaining informed consent. Paul raises concerns about the practice of informed consent during mass immunisation as part of the Polio Eradication Initiative in India (Paul, 2005). He points out that the benefits of polio immunisation are overstated whilst risks are understated and brings up the issue of non-disclosure.[24]

Developed countries like the United Kingdom and the United States America have a written policy on obtaining consent, which is a legal requirement for administering a vaccine (National Childhood Vaccine Injury Act cited by Malone 2003: 268; Bradley 1999: 330-334). Although informed consent for immunisation services is practiced in these countries the setting and the constraints faced in developing countries and in South Africa make it difficult for the practice of fully informed consent. There is little doubt that informed consent has its limitations and when it comes to public health

[24] Paul highlights the concerns that parents are not told about the serious risk of developing vaccine associated paralytic polio (VAPP) due to the fear of dropping immunisation coverage rates which in turn will undermine the objectives of the programme. He points out that the VAPP incidence is much higher in India than expected and realised. The high VAPP incidence in India has been reported by others (John 2004), referred to in the next session on risk of vaccines.

programmes this may not be practical. Consequently, others have questioned the applicability of informed consent in exercise of public health programmes.

In South Africa, there are two opportunities for providing information on immunisation services: through health promotion talks which are usually offered in the waiting area and by the vaccinator when immunisation is administered. The adequacy of the information offered during immunisation sessions on the benefits and associated risks of immunisation may raise ethical concerns. The health promotion sessions cover a wide range of health topics and immunisation is one amongst a number of health topics covered. The health promotion sessions are not uniformly provided in all facilities and not all facilities have the staff to provide this service. The information given by vaccinators generally relates to minor commonly experienced side effects like: mild temperature, persistent crying, swelling at injection sites and the date for the next visit. The EPI reviews conducted in provinces report that in a number of facilities there is lack of uniformity in information given to mothers about side effects and contra-indications (Eastern Cape Department of Health, 1998). Reports from two other provinces indicate that there is adequate information given to mothers about side effects (KwaZulu Natal Department of Health Nov 1998; Northern Province Department of Health May 1998).

It may be safely assumed that the interpretation of what constitutes adequate information in these reports did not have the ethical perspective and relates to information about common minor side effects and not to rare but serious effects. It is certain that the vaccinators hardly if ever refer to the risk of developing encephalitis and of developing say vaccine associated poliomyelitis. Whether it is necessary that parents should be informed about these very rare side effects in this setting is debatable; thus

the focus will be on disclosure of common side effects which may be a cause for inconvenience and anxiety to a parent. Using this standard, the parents are in many instances not informed of the side effects, thus there is limited disclosure which raises concerns on the ethics of this practice.

There is also no written consent form that is filled and signed by parents and care-givers before a child is vaccinated during the provision of routine services. It is generally assumed that consent is implied by the parent or care-giver bringing the child to a facility for immunisation. The same practice applies to the treatment of clients with minor ailments. Although it may be argued that due to the fact that immunisation is provided to healthy individuals it should be treated more strictly. This may not be a valid argument. Nevertheless, adequate information and on the common side effects should be provided. The low level of literacy particularly in more remote settings presents a further limitation in the options that could be used to inform clients about immunisation.

Similarly with regard to privacy during an immunisation session, the situation differs from facility to facility. Whilst in some facilities there is a reasonable level of privacy during routine immunisation sessions, in that one client is seen at a time in a consulting room; there are a large number of facilities where vaccines are administered in view of other users and other facility staff not attending to a particular client.

Immunisation campaigns present a different scenario. Consent forms are filled by the parents a couple of weeks or so before a campaign for the children at crèches and pre-schools. The children who present to health facilities have no consent forms. The teachers at pre-schools distribute the consent forms to parents/care-gives and follow up

with them to bring back the consent forms before the dates of an immunisation campaign. The information on the form is limited as it mainly informs on the dates of the campaign and which vaccines are administered. A statement on the safety and effectiveness of the vaccines is included. Common side effects like mild fever and local reactions are mentioned. Mention is made to serious side effects that are rare, and much rarer than the effects of the disease itself. There is no mention of what exactly these serious rare side effects are; parents are encouraged to contact the programme should they require additional information (Campaign field guide – NDOH 2007).

With respect to privacy, the campaign setting and services present a much poor picture. During immunisation campaigns a large number of children are vaccinated at the same time. To ease the work load and work faster, in many facilities children are vaccinated in groups of five in a one room or designated section of a bigger hall. In this setting, immunisation services are offered in the open, in full view of those who are still waiting and passers by.

Issues that may raise concern at the facility level where the health care worker (HCW) interacts with the client and the constraints that affect other health services have been raised in this section. It may not be practical in this country to provide a kind of service during an immunisation session that represent an ideal ethical practice where there is full privacy for patients, full disclosure of information and the parents are given an opportunity to consent to immunisation even if its not signed but verbal, due to the constraints already highlighted. However, it is possible to address some issues like: providing parents and care- givers with more information on the risks and benefits of immunisation during health promotion talks and through posters as well as information

brochures that can be freely available at the waiting areas. Caution will have to be exercised so as not to provide too much information, which may actually cause undue fear and anxiety leading to refusal of immunisation services. Such an outcome may actually present harm to the children and to the country. It will be necessary to weigh and balance the amount of information provided, so it is adequate without information overload. To this effect it may be worthwhile to conduct some studies on this area and look more closely at the detail of information that should be shared with the public and test information provided at different levels of detail.

Effective supervision of PHC services will help improve the general quality of services. This will help reduce the risks associated with provision of health services. Currently there is no prioritisation of supervision of EPI services. Supervision for immunisation services need to be prioritised as these services are offered to healthy individuals and tolerance for harm associated with immunisation services is may be much lower than for curative services. This point needs to be highlighted with health managers who in turn should ensure that prioritisation of immunisation services is addressed.

It is difficult to see how the issue of lack of privacy during campaigns can be adequately addressed with the available resources. The nature of the campaigns makes this situation inevitable, as for campaigns demand that a large number of children should be immunised within a short period of time for campaigns to be effective. This means that facilities have to deal with large numbers daily for the whole duration of the campaign. However, privacy during routine immunisation should be approached as part of continuous improvement efforts by the department of health at all levels: from national, provincial, district up to facility level.

7.2 Risk in relation to EPI vaccines

Vaccines offered in the immunisation policy are against: polio, measles, diphtheria, tetanus, pertussis, haemophilus influenza type b (Hib), hepatitis B and tuberculosis. Vaccines used in the EPI in South Africa meet the international standards set by WHO and UNICEF. Furthermore, South Africa has an additional requirement by the Medicines Control Council (MCC), in terms of regulation 44 of the Medicines and Related Substances Act, Act 101 of 1965, that each batch of vaccines, which already meets the WHO requirement, should be tested for safety at the National Control Laboratory (NCL) in Bloemfontein before it can be released. Consequently this requirement is considered in vaccine logistics and in estimating vaccine delivery.

Notwithstanding the huge benefits of vaccines, vaccines are not absolutely without risk. To reduce the risk associated with vaccines, research and development on new vaccines and new approaches to immunization is ongoing. Manufacturers continually offer newer formulations and vaccine combinations, which are more purified with a lower risk profile than earlier products. Furthermore, a risk associated with a particular infectious disease changes over time. This necessitates a continual review of the: the type of vaccines offered and the risk associated with specific vaccines. These must be weighed against the risk of a particular disease at that time. Therefore, the resultant risk-benefit ratio of a specific vaccine is not static.

The use of acellular pertussis and inactivated polio vaccines in many developed countries represent the continual shift to the use of vaccines with a lower risk profile. Concerns over the safety and reactogenicity of whole cell pertussis vaccines resulted in

the development of acellular pertussis, which is less reactogenic but has similar protection levels. However, the level of safety for severe adverse reactions for acellular and whole cell pertussis appears to be the same (Braun 2000). The USA and many European countries including the UK, Sweden, Germany and France now use acellular pertussis vaccine. A similar move has been seen with the use of inactivated polio vaccine due to concerns over the risk of paralytic poliomyelitis associated with the live attenuated oral polio vaccine. Data from WHO indicates that by December 2006 there were 42 countries using acellular pertussis and 32 using injectable polio in their national immunisation programmes (personal communication & sharing of data with WHO Head Quarters through WHO Regional Office, Harare). It is with this background that we focus on the vaccine formulations used in EPI – SA and on the risk associated with some of vaccines relative to the risk of a particular disease.

The DT (diphtheria and tetanus), measles, bacillus calmette-guerin (BCG), hepatitis B and haemophilus influenzae type b (Hib) vaccines used in the EPI in SA are similar to those used in many developed countries; are thus not discussed any further. The formulations of pertussis and polio vaccines may be a cause for concern. The EPI in South Africa uses whole cell pertussis, not the acellular pertussis used in many developed countries which has been used in the USA since 1998. Similarly with polio vaccines, SA still uses oral polio vaccine (OPV) which has been associated with a risk of developing vaccine associated paralytic polio (VAPP).

The oral polio vaccine (OPV) has been used extensively all over the world as a strategy of the global Polio Eradication Initiative. OPV is used in the polio eradication strategy particularly during the time of high transmission of wild poliovirus and in countries with

persistent transmission of wild poliovirus. The distinct qualities and advantages of OPV that made it the vaccine of choice for polio eradication activities include: the ease of administration; low price compared to IPV; high efficacy; its ability to spread to un-immunised contacts causing them to develop immunity against polio and effectively blocking wild poliovirus transmission (Kew 2004:16-23). Therefore OPV is much more effective in achieving herd immunity particularly in developing countries where socioeconomic conditions favour the spread of infections like polio, transmitted through the oral – faecal route.

Despite its many advantages, OPV carries the risk of vaccine associated paralytic poliomyelitis (VAPP) in the recipient. The occurrence of VAPP varies widely; from 1 case per 2,9 million OPV doses in the USA, to 0,4 – 3 per million vaccinated children in European countries up to 7 cases per million birth cohort in India. India has one of the highest VAPP incidence in the world (Alexander 2004: 1696-1701; John 2004:).

Another complication of OPV is that in countries where OPV coverage is low, the use of OPV has been shown to cause paralysis in contacts of recipients due to a circulating vaccine derived poliovirus (cVDPV) (Kew 2004). The cVDPV is a result of a vaccine derived poliovirus which mutates, becomes virulent and circulates in the community to infect those who do not have adequate immunity levels. The mutated virulent virus then infects contacts of vaccine recipients and causes paralysis in them, in the same way that a vaccine virus (that has not become virulent) can result in protection of contacts. Therefore, that where the risk of wild poliovirus infection is low and the economy allows, the use of IPV is preferable. Outbreaks associated with cVDPV have been described in Hispaniola in 2000-01, in Philippines in 2001 in Madagascar in 2002 and in Egypt from

1983 to 1993 (Kew 2004:16-23). It is for these reasons that many developed countries use IPV to eliminate the risk associated with OPV.

In the USA, the last case of wild poliovirus was in 1979. During the period of 1961 to 1989, there was an average of 9 VAPP cases per year as a consequence of OPV use. Considering this burden of VAPP cases, in 1997 the national vaccination policy was changed from total reliance on OPV to a sequential schedule that starts with inactivated polio followed by OPV; and by the year 2000 the USA used only IPV in the immunisation programme. The change in policy resulted in an elimination of VAPP when only IPV was used (Alexander 2004: 1696-1701).

These issues have significant risk benefit implications for the immunisation programme in this country. The last laboratory confirmed wild poliovirus case in this country was in 1989 (Ngcobo 2008: 9-13). Four (4) national rounds of polio immunisation campaigns have been conducted since 1996. In 2006, the Africa Region Certification Commission (ARCC) accepted the “National Documentation for the Certification of Poliomyelitis Eradication: South Africa” thereby declaring that the country had interrupted wild poliovirus transmission (National Certification Committee - South Africa 2006). Although the risk for wild poliovirus importations remains, due to ongoing poliovirus transmission in some countries in Africa, the justification for a country like South Africa to continue to use OPV despite the well documented risks is questionable. Notwithstanding the fact that there is no documented case of VAPP in this country, the risk remains. Furthermore lack of sensitive specific surveillance for VAPP cases and lack of accurate data may explain the absence of documented VAPP cases. It can be argued that the country has enough resources to consider the implementation of inactivated polio (IPV). Considering

that Nigeria remains the only country in the Africa region endemic of wild poliovirus (WHO 2006), this should be the appropriate time for changing over to injectable polio vaccine. The use of IPV in this country becomes more compelling when one considers that there is no compensation scheme to provide for the unfortunate ones who may develop such adverse effects from immunisation, like VAPP.

A similar argument applies to the use of the whole-cell pertussis vaccine. South Africa continues to use whole-cell pertussis in the EPI. However, acellular pertussis vaccine use is available and used in the private sector. Based on the background and the level of development this country has reached it is fit that the use whole-cell pertussis and the associated risk should be assessed with the view of switching to acellular pertussis. Furthermore, one does not want to create or endorse the perception that government programmes provide inferior products compared to the private sector. This move may be further supported by the proportion of AEFI cases associated with DPT-Hib use which are much more than those associated with the other antigens (AEFI data, Nat DOH).

A decision to switch to injectable polio vaccine or acellular pertussis will have cost implications. However the incremental cost of changing to safer formulations should be weighed against the cost the programme may face should serious AEFI occur. Such cost will include damage to the image of the programme and possible court cases which may result from litigation. If a serious AEFI occurred with the use of whole-cell pertussis vaccine or OPV there could have grave consequences for the image of the programme which may cause the public to lose trust in the immunisation programme.

There is a definite need to promptly review the risk benefits associated with the use of whole cell pertussis and OPV vaccines and seriously consider the use of acellular and IPV vaccine. This will help define a proactive risk management approach for a programme directed at healthy individuals for public protection. There is a strong moral background for the immunisation programme to adopt this approach, which leaves little room for litigation and attack by anti-vaccination lobbyists.

Furthermore, risk consideration should extend to other vaccines and ensure some form of protection for vaccine recipients who may be unfortunate to suffer vaccine injury. This demands establishment of a compensation programme that covers adverse events from all the vaccines in the EPI schedule. The moral justification for this is that society will share the benefits as well as the risks associated with immunisation. The risk can be shared through taxes that can be levied on individuals to fund such a compensation programme. Such a compensation programme will ensure a programme that is delivered in line with the principle of justice through just distribution of benefits and burdens.

7.3 Monitoring of Adverse Events Following Immunisation (AEFI)

To ensure vaccine safety and monitor programme performance, many immunisation programmes around the world monitor the occurrence of adverse events following immunisation (AEFI). In South Africa the surveillance for AEFI was implemented in 1997 (personal communication, EPI – national office). Surveillance for AEFI forms part of surveillance for EPI targeted conditions like measles, acute flaccid paralysis (AFP) and neonatal tetanus. This surveillance is conducted by the EPI unit, separate from that conducted by the Medicines Control Council (MCC) through the National Adverse Drug Event Monitoring Centre (NDEMC) in Cape Town. The National Adverse Drug Event Monitoring Centre forms part of the National Pharmacovigilance Programme conducting post marketing surveillance. Information is shared between these two programmes i.e. NDEMC and EPI.

Training on immunisation conducted by the national and provincial offices normally includes AEFI. Surveillance forms are generally available in all health facilities around the country. Investigations are conducted on all serious cases, which include all cases admitted to hospital and deaths presumed to be associated with immunisation. Staff from the district and provincial offices conducts the investigation. The national office is involved in the investigation of all cases that involve death and other serious cases, like where a post mortem is needed and cases which involve the media. Determining causality is a challenge, as a number of cases particularly deaths may be attributed to immunisation when immunisation is not the cause. This is similar to experiences of other AEFI monitoring systems. The high prevalence of HIV/AIDS in this country is another compounding factor, due to number of children already sick from HIV who may die within

a few days after immunisation due to an HIV related illness. In such cases, the fact that the child was recently immunised is merely coincidental. However, health workers and particularly the parents often find it difficult to separate the two and often assume that immunisation is the cause of death (NDOH, AEFI Surveillance data, National 2003-2006, unpublished).

There is no standing committee at national office that reviews and classifies AEFI cases. A committee that was functional in 2000 in response to a court case of a child presumed to have died from DPT-Hib immunisation, stopped functioning when the case was closed. It is reported that KwaZuluNatal province has a standing committee that reviews and classifies all AEFI cases from this province. There is no indication of any other province with a similar committee (personal communication EPI-SA national office and with KwaZuluNatal EPI Manager). This means that, at national level the programme has no proper system of reviewing the quality of surveillance and classification of AEFI cases. This is of particular concern for serious cases perceived to be associated with immunisation.

Data from the NDOH EPI indicates that the rate of AEFI in the last 3 to 4 years range from 50 to 90 cases a year. DPT-Hib vaccine is associated with the highest number of AEFI compared to other vaccines followed by BCG. All reported deaths presumed to be associated and fully investigated, have been found to be coincidental (unpublished data, AEFI surveillance 2003-2006, NDOH). The sensitivity and quality of the surveillance for AEFI is an area that has not been studied. There may be concerns regarding the sensitivity of reporting and level of health worker awareness on reporting AEFI. It is expected that the number of AEFI cases should be roughly proportional to the number of

vaccine doses administered. This means that all things equal, provinces with a large target population and thus administer a large number of vaccine doses will be expected to have more cases of AEFI compared to provinces with a smaller target population. This is not the case, as it is not reflected in the AEFI surveillance data. AEFI cases generally originate from a few provinces like KZN, Mpumalanga and Western Cape that have higher levels of reporting with other provinces having much fewer cases or being quiet. (AEFI surveillance 2003-2006 NDOH, unpublished)

Based on the data and information from the NDOH it appears that the AEFI monitoring system needs to be strengthened. This should include ongoing training and sensitisation of health workers, ensuring full investigation of cases with visits of the affected families. Considering that in countries like the USA, surveillance of AEFI is mandated by legislation, this places a compelling need for this country to set up a Committee of experts to review serious AEFI cases. Such a committee could consist of: paediatricians, neurologists, epidemiologists, public health specialists and medico–legal experts to assess all serious AEFI cases, properly classify cases, continually appraise the AEFI monitoring system and recommend appropriate compensation for serious adverse events when such a system is in place.

8. Recommendations and Conclusion

Recommendations

Although this study was on ethical aspects some issues raise legal aspects, therefore the recommendations have a bearing on policy and legislation. The primary objective of the recommendations is to position the immunisation programme in South Africa such that despite the constraints faced, it is responsive to ethical concerns related to the programme. The aim is an immunisation programme that is proactive in addressing risk issues through a system that will avoid litigation. In order to achieve this, the following recommendations are made.

Policy Review

The Director: Child and Youth Health, overseeing the EPI programme at the National Department of Health should revise the EPI policy to address the following recommendations:

i) Policy should be reviewed to ensure that supervision for EPI services is prioritised. Health Managers at all levels should be alerted to this need.

ii) All health facilities offering immunisation services should provide adequate information on immunisation to parents and care givers. The information should cover the benefits and the risks associated with immunisation. Where literacy levels are low, structured and regular health promotion talks before immunisation sessions should be conducted.

iii) The decision making process on rendering the immunisation services should ensure meaningful involvement of appropriate community members at all levels

from national, to province, district, municipality right up to facility level. The immunisation policy should reflect this.

iv) The immunisation policy should require a continual assessment by experts at determined intervals of risk–benefit issues of certain vaccine antigens and vaccine preventable diseases. The assessment of risk posed by OPV and whole-cell pertussis vaccines is now due.

v) The surveillance system and management of Adverse Events Following Immunisation (AEFI) should be strengthened with ongoing training and sensitisation sessions for health workers to ensure a high level of sensitivity and an effective response to serious incidents.

Legislation Review

The Director General: Health, should establish a comprehensive piece of legislation that will deal with immunisation services, which will address the following areas:

i) A Compensation System for those who suffer serious adverse events following immunisation should be established to ensure a well structured compensation process to address this risk. Legislation should mandate the development of Compensation System and a Compensation Fund for the proposed system.

ii) Surveillance of AEFI should be mandated by law. An AEFI should therefore be a notifiable medical condition and should be included in the list of medical conditions under the National Health Act 2003 (Act NO. 61 of 2003).

iii) The proposed legislation should provide for formation of an independent AEFI Committee of experts will regularly review all serious cases of adverse events

following immunisation (AEFI), classify them and identify those eligible for compensation.

iv) Continual review and assessment of risk benefit ratios for different conditions covered by EPI at intervals of 5 years should be required by law. An efficient AEFI surveillance system will provide crucial information required for this exercise.

Conclusion

Universal immunisation is ethically defensible based on the various ethical theories and principles. South Africa's experience with the measles outbreak in 2003 to 2005 does not only demonstrate the compelling need to continue with the provision of universal immunisation services and maintain high coverage levels; it points to the existence of a social contract. Therefore, there is no moral basis for individuals to refuse to have their children vaccinated except when it is medically contraindicated. However, there remains room for improvement of ethical practices at service delivery. The risk–benefit elements for each vaccine and the profile of targeted diseases are continually changing. Thus, there is a need for ongoing assessment of risk benefit issues to ensure the use of appropriate vaccines with optimal safety. The recommendations aim for an immunisation programme of an acceptable ethical standard and that addresses the main risk issues associated with immunisation by establishing a legislated compensation system.

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Annexure A : Human Research Ethics Committee Clearance Certificate